Title Slide: Implementation Science Approaches to Integrating Cancer Survivorship Research into Practice and Policy: Models, Methods, and Measures

Russell E. Glasgow, Ph.D.
Deputy Director,
Implementation Science Team
Division of Cancer Control and Population Sciences
June 14, 2012

[Image] Series of pictures depicting Washington, DC sites [End Image]

Slide 1: NCI Implementation Science Team Vision

To achieve the rapid integration of scientific evidence, practice, and policy, with the ultimate goal of improving the impact of research on cancer outcomes and promoting health across individual, organizational and community levels.

[Image] Picture of the Washington Capital building [End Image]

Slide 2: Models, Methods and Measures for Survivorship from Implementation Science

- Models: T0-T4 and Key Lessons Learned
- Methods:
    - Types of Evidence Needed
    - RE-AIM Framework
    - Measures:
    - Care Planning
    - D and I measures (context, implementation, costs)

Slide 3: D&I Definitions (aka KT)

"Dissemination is the targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intent is to spread knowledge and the associated evidence-based interventions." (scale-up)
"Implementation is the use of strategies to adopt and integrate evidence-based health interventions and change practice patterns within specific….settings"

Slide 4: Dissemination and Implementation Research Characteristics

- Contextual
- Complex
- Multi-component programs and policies
- Non-linear
- Transdisciplinary
- Multi-level and multi-method
- Addresses "wicked", messy, important problems

Brownson, R, Colditz, G, and Proctor, E (Eds.). Dissemination and Implementation Research in Health. New York: Oxford University Press, 2012.
Glasgow, R. E. & Chambers, D. Clin Transl Sci 2012:5, 48-55

Slide 5: The Translational Science Process for Survivorship

[Image] The framework for the continuum of multidisciplinary translation research builds on previous characterization efforts in genomics and other areas in health care and prevention. The continuum includes four phases of translation research that revolve around the development of evidence-based guidelines. "Survivor Population Health; Disease Burden; Public health impact *(Surveillance indicators)*" is connected to "Scientific Discovery (*preclinical, epidemiology mechanism studies)*" (T0) which is connected to "Tests of promising Interventions *(Phase I, II, & III trials)*" (T1) which is connected to "Evidence based Recommendations & policies (Guidelines)" (T2), which is connected to "*Implementation* into Practice, Organizations, and Communities" (T3). "*Implementation* into Practice, Organizations, and Communities" completes the circle and is connected to "Survivor Population Health; Disease Burden; Public health impact *(Surveillance indicators)*" (T4). At the center of the figure is a box titled "Knowledge Integration (Management, Synthesis and Stakeholder & Survivor Engagement)". The box is connected by bi-directional arrows to each of the phases (T0-T4) of the pentagon described above. [End Image]

Modified from: Khoury MJ, Gwinn M, Ioannidis JP American Journal of Epidemiology, 2010, 172:5 pg. 517-24.

Slide 6: Implications of T0-T4 model

- Progress is not linear
- Knowledge integration involves "knowing where we are going"; not getting stuck at T0-T2
- There is "basic" research at each level of T0-T4
- Need respect and convergence across methods, disciplines, and "stages" of research
- Stakeholder involvement is essential—throughout

Slide 7: Most Common Research Translation: Bench to Bookshelf

[Image] Clinician looking at vial and writing notes with arrow pointing to books covered in cobwebs [End Image]

Slide 8: Abundance of D&I Models—61 at Least; But There are Key Common Points:

- Context is critical
- Begin with stakeholders—take their perspective
- Design for dissemination—from beginning—cannot wait until the end
- Need balance between fidelity to evidence-based program and adaptation to local setting

Slide 9: Key Common Points (cont.)

- There is more than evidence needed for successful adoption, implementation and sustainability
- D&I Science is a multi-level affair
- Select the DESIGN and the MODEL that best fits your question—less important WHICH model than that you use it well
- Need to focus on *replication, relevance, transparency, and costs*

Slide 10: Types of D & I Methods and Evidence Needed: 2R's and "RCT"

- Relevant
- Rigorous and
- Rapid
- Cost informative
- Transparent

Glasgow R, *Annals of Behavioral Medicine, 2008, 35:* 19-25.
Glasgow R, Chambers D. *Clinical and Translational Science*, 2012, 5(1):48-55
http://cancercontrol.cancer.gov/IS/

[Image] Picture of DC Justice Department [End Image]

Slide 11: Relevant (Contextual and Practical)

- Relevant to *stakeholders* (patients/family, clinicians, administrators, policy makers)
- Relevant *samples*—representative of real- world, including patients with co-morbid conditions
- Relevant *settings*—similar to those in practice (not just the most advanced and well resourced)
- Relevant *staff*—including those who have other duties and competing demands

Slide 12: Why is D&I Relevant to Survivorship? Ultimate Impact of "Evidence Based Intervention X"

[Table]

Dissemination	Concept	% Impacted
50% of Clinics Use	Adoption	50%
50% of Practitioners Recommend	Adoption	25%
50% of Patients Accept Recommendation/Attempt Change	Reach	12.5%
50% Follow Regimen Correctly	Implementation	6.2 %
50% of Those Implementing Correctly have Substantial Benefit	**Effectiveness**	**3.1%**
50% Continue to Adhere/Benefit After 6 Months	Maintenance	1.6%

[End Table]

Slide 13: Moral of the Story?

1. "Focus on the Denominator" (not just the numerator)
2. Each step of the dissemination sequence or each "RE-AIM" dimension is important

http://www.re-aim.org

Slide 14: RE-AIM Realist* Question:

- What percent and types of patients are Reached;

- For whom among them is the intervention Effective; in improving what outcomes;
- In what percent and types of settings and staff is this approach Adopted;
- How consistently are different parts of it Implemented at what cost to different parties;
- And how well are the intervention components and their effects Maintained?

*Pawson R, et al. *J Health Serv Res Policy* 2005;10(S1):S21-S39.
Gaglio B, Glasgow RE. Evaluation approaches…In: Brownson R, Colditz G, Proctor E, (Eds). *Dissemination and implementation research in health: Translating science to practice*. New York: Oxford University Press; 2012. Pages 327-356.

Slide 15: RE-AIM Survivorship Care Plan (SCP) Example:

- In what percent and types of patients are SCPs Received;
- For whom among them is the intervention Effective; in improving what outcomes; what broader effects and negative consequences?
- Among what percent and types of settings and practitioners are SCPs Adopted;
- How consistently are different parts of SCPs Implemented across different settings, clinicians, and patient subgroups, and at what cost;
- And how well is the SCP program and its effects Maintained?

Slide 16: Rigorous….and a Word about RCTs

- Address most likely challenges to validity and conclusions for THAT question
- Both external and internal validity are important
- Design should fit the question—NOT vice-versa[1]
- An RCT is not an RCT is not an RCT
- CONSORT delineation of pragmatic trials is an important advance[2]
- RCT is not the only design that is experimental—and it does NOT guarantee causality[3,4]

[1] Mercer S et al. Amer J Prev Med, 2007; 3:, 139-154.
[2] Thorpe et al. J Clin Epidem 2009; 62: 464–475, Can Med Ass J 2009; *180,* E47-E57.
[3] Kessler & Glasgow, Amer J Prev Med, 2011, 40, 637-644;
[4] Cartwright BioSocieties, 2007, 2: 11-20.

Slide 17: Rapid Evidence

- Need rapid learning research—especially for pressing issues such as obesity, HIV, explosion of health care spending, health inequities, and cancer survivorship
- EMRs, and their potential enhancements, make possible "rapid learning health care systems"*
    - *Real-time data on millions of real-world patients in real-world health care settings, treated under usual conditions*

Institute of Medicine, A Foundation for Evidence-Driven Practice: A Rapid Learning System for Cancer Care, 2010. http://www.iom.edu/Reports/2010/A-Foundation-for-Evidence-Driven-Practice-A-Rapid-Learning-System-for-Cancer-Care.aspx
Etheredge L et al, *Health Affairs, Web Exclusive Collection,* w107-w118, doi:10.1377/hlthaff.26.2.w107)

Slide 18: How to Evaluate Technologies that Outpace Research?

[Image]
A figure showing how standard grants are outpaced by technology.

A timeline going from 2005 to 2011. On the top, is a series of boxes showing at what point major technology innovations occurred: YouTube (2005); iPhone (2007); Android (2008); iPad (2010). On the bottom, is a series of boxes showing the key events of a grant: Grant Submit and Award (2005); Development and Pilot Testing (2006-2007); Recruit and Randomize (2008-2009); Follow-ups (2009-2010); Analyze and Publish (2011). [End Image]

William Riley, NHLBI and NCI

Slide 19: Cost Evidence

- Replication costs and scalability costs are arguably most needed
- Perspective— that of patient and adopting setting
- Costs should be comprehensive and transparent
- "One persons costs are another's profits"
- Should be harmonized and include costs frequently not counted that need to be—e.g., recruitment, overhead, training, preparation and supervision[1]
- Cost collection and cost-effectiveness analyses need not be overwhelming*--cost per incremental unit change

[1] Ritzwoller et al, Trans Behav Med, 2011*, 1,* 427-435.

Slide 20: Transparent Evidence on…..

- Info needed to *replicate* or implement
- *Resources required*—costs for patients and delivery setting perspectives
- How were settings, clinicians, and patients selected—(who *was excluded and why*)
- *Adaptation*—changes made to protocol, to intervention, to recruitment, etc.
- *Differences across settings*

Slide 21: Future Evidence Needs and Opportunities—Keys to Advance Translation

- Context—key factors that may moderate results
- Scalability—potential to impact large numbers
- Sustainability
- Health equity impacts
- Patient/citizen/consumer and community perspective and engagement throughout
- Multi-level interactions, especially between policy and practice

Slide 22: All Models (and Methods) are Wrong….Some are useful

"To every complex question, there is a simple answer…and it is wrong."
~H. L. Mencken

Slide 23: Need for Better and Harmonized Measures in D&I and Survivorship Research

- Most studies use their own measures, often unknown characteristics, and quite different measures same construct
- Without standard or more harmonized measures, difficult to do reviews, syntheses, compare across studies
- Are different purposes of measurement—e.g.:

"Gold standard"—when this is primary focus for grant, need "best possible measure", have staff to ensure quality
"Practical measure"—for use in busy, low-resource settings; when one of a large set of measures; has to be brief and feasible

Slide 24: Care Planning and D&I Measures Initiatives

[Image] Screenshot of GEM homepage [End Image]

https://www.gem-beta.org/ (GEM Homepage)
http://cancercontrol.cancer.gov/IS/resources.html (IS Team Website)
http://dccps.nci.nih.gov/ocs/ (Office Cancer Survivorship)
[Image] Logos for the Cancer Communication Research Center; NIH; HHS; and NCI. [End Image]

Slide 25: Research to Reality (R2R): A Virtual Community of Practice

A dialogue between practitioners and researchers on how to move evidence-based programs into practice

- Launched February, 2011 (NCI): Linked to Cancer Control P.L.A.N.E.T. Step 2
- Site Features:
  - Monthly cyber-seminars
  - Discussion forums
  - Mentorship program
  - An events calendar
  - Featured partners
  - Community profiles

https://ResearchtoReality.cancer.gov

Slide 26: Cancer Control P.L.A.N.E.T.

[Image] Screenshot of the Cancer Control P.L.A.N.E.T. Homepage [End Image]
http://cancercontrolplanet.cancer.gov

Slide 27: Research Tested Intervention Programs (RTIPs)

[Image] Screenshot of RTIPs search page [End Image]
http://rtips.cancer.gov/rtips/programDetails.do?programId=308006

Slide 28: The Translational Science Process for Survivorship

[Image] The framework for the continuum of multidisciplinary translation research builds on previous characterization efforts in genomics and other areas in health care and prevention. The continuum includes four phases of translation research that revolve around the development of evidence-based guidelines. "Survivor Population Health; Disease Burden; Public health impact *(Surveillance indicators)*" is connected to "Scientific Discovery (*preclinical, epidemiology mechanism studies)*" (T0) which is connected to "Tests of promising Interventions *(Phase I, II, & III trials)*" (T1) which is connected to "Evidence based Recommendations & policies (Guidelines)" (T2), which is connected to "*Implementation* into Practice, Organizations, and Communities" (T3). "*Implementation* into Practice, Organizations, and Communities" completes the circle and is connected to "Survivor Population Health; Disease Burden; Public health impact *(Surveillance indicators)*" (T4). At the center of the figure is a box titled "Knowledge Integration (Management, Synthesis and Stakeholder & Survivor Engagement)". The box is connected by bi-directional arrows to each of the phases (T0-T4) of the pentagon described above. [End Image]

Modified from: Khoury MJ, Gwinn M, Ioannidis JP American Journal of Epidemiology, 2010, 172:5 pg. 517-24.

Slide 29: Take Home Points

- There is a pressing need for a DIFFERENT type of research — "D&I" that translates more rapidly, and is more relevant to stakeholders
- This field is still emerging, but there is agreement on key common points among different models of D&I research
- There are many opportunities for this type of research, especially among networks including the Livestrong, VA, CRN, PBRN, cancer center, CTSA and community networks

Slide 30: Questions/Comments

Contact me: glasgowre@mail.nih.gov
IS Team Website: http://dccps.cancer.gov/is/

Slide 31 (extra): Linking Patient, Physician, and Community Programs

[Figure] three boxes form a triangle with connecting arrows. Box 1, "Family, Friend, Peer Network" is connected to box 2, "Health Care System." The connecting arrows indicates this connection is through "Informed Referrals and Support Opportunities" and "Patient Preferences and Status." Box 2, "Health Care System" is then connected to Box 3, "Larger Orgs/Networks" through "Informed Referrals" and "Feedback on Patient Progress." Finally, Box 1 and 3 are connected through "Promotion of targeted Evidence-based Programs" and "Update on Progress." At the center of the triangle is a smaller triangle titled, "Successful PCP- Community Link." At each corner of the triangle by the outside boxes is labeled. By box 1, "Engaged Patient", by Box 2, "Informed, Supportive System" and by Box 3, "Evolving Evidence-Based Community Program and Resources." The entire figure exists within the broader multi-level context identified as: intrapersonal/biological; interpersonal/family; organizational; policy; community/economic; social/environment/historical. [End Image].